United States
Environmental Protection
Agency

Office of Air Quality
Planning and Standards
Research Triangle Park, NC 27711

EPA-456/R-97-004
September 1997

Air

EPA

ETHYLENE OXIDE COMMERCIAL STERILIZATION AND FUMIGATION OPERATIONS NESHAP

IMPLEMENTATION DOCUMENT

ETHYLENE OXIDE COMMERCIAL STERILIZATION AND FUMIGATION OPERATIONS NESHAP IMPLEMENTATION DOCUMENT

Prepared for:

Program Review Group
Information Technology and Program Integration Division
Office of Air Quality Planning and Standards
U. S. Environmental Protection Agency
Research Triangle Park, NC 27711

Prepared by:

Midwest Research Institute
Crossroads Corporate Park, 5520 Dillard Road, Suite 100
Cary, North Carolina 27511

September 1997

Disclaimer

The information provided in this document is intended as supplemental information to the regulated community. In case of any discrepancy between information provided in this document and the codified National Emission Standards for Hazardous Air Pollutants for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O), information contained in the codified standards will apply.

Mention of trade names or commercial products is not intended to constitute endorsement or recommendation for use. Copies of this report are available through the library Services Office (MD-35), U. S. Environmental Protection Agency, Research Triangle Park, NC 27711, or from National Technical Services, 5285 Port Royal Road, Springfield, Virginia 22161

TABLE OF CONTENTS

TABLE OF CONTENTS (continued)

LIST OF FIGURES

LIST OF TABLES

CHAPTER 1
INTRODUCTION

1.1 BACKGROUND

Under Section 112 of the Clean Air Act (CAA), the U. S. Environmental Protection Agency (EPA) is required to develop national emission standards for hazardous air pollutants (NESHAP) for source categories that have been identified as major sources of hazardous air pollutants (HAP). Section 112(b) of the CAA identifies ethylene oxide (EO) as a HAP because it is suspected to cause cancer in humans, is highly mutagenic and teratogenic, and has significant acute and subchronic exposure health effects. To meet the requirements of the CAA, EPA promulgated NESHAP for ethylene oxide commercial sterilization and fumigation operations in the December 6, 1994 *Federal Register* as subpart O of part 63 of the Code of Federal Regulations.

Under this NESHAP, the EPA has elected to regulate both major (i.e., sources that emit or have the potential to emit 10 tons per year or more of any HAP or 25 tons per year or more of any combination of HAP) and area sources (i.e., any HAP source that is not a major source) because of the high toxicity of EO. Therefore, consistent with section 112(d) of the CAA, existing and new major sources will control emissions to the level achievable by the maximum achievable control technology (MACT); existing and new area sources will control emissions using generally available control technology (GACT).

Commercial sterilization and fumigation sources using EO as a sterilant for heat and moisture sensitive products and as a fumigant to control microorganisms or insects are subject to the regulation. However, the regulation exempts EO sterilizers in hospitals. Products that are typically sterilized or fumigated with EO include medical equipment and supplies, pharmaceuticals, spices, books, museum artifacts, and cosmetics. Approximately 200 EO commercial sterilization and fumigation sources exist in the United States; approximately 150 of these sources are expected to be affected by the regulation. The EPA estimates that full compliance with the regulation will reduce the amount of EO released into the air by 1,100 tons.

1.2 PURPOSE OF DOCUMENT

Under sections 112(d) and 112(l) of the CAA, EPA provides guidance useful to EPA Regional Office and State and local agency personnel who will be responsible for implementing NESHAP. The purpose of this document is to provide these personnel with implementation materials to assist them in conducting complete and efficient inspections at ethylene oxide commercial sterilization and fumigation operations to determine compliance with the NESHAP.

1.3 ORGANIZATION

Chapter 2 of this document presents a summary of the requirements of the regulation. Strategies for determining applicability of the regulation, including flowcharts, are provided in Chapter 3. Chapter 4 discusses the emission reductions and limits in the regulation and the control techniques that may be used to meet these standards. Requirements for demonstrating compliance with the regulation are discussed in Chapter 5. Chapter 6 summarizes the recordkeeping and reporting requirements of the regulation. Chapter 7 covers inspection procedures, including inspector checklists. A summary of commonly asked questions and answers are included in Chapter 8, and a list of other available implementation materials is included in Chapter 9. Appendix A contains a glossary of terms and nomenclature used in the regulation. A detailed “table of contents” of the regulation is included as Appendix B. A list of known facilities is included as Appendix C.

CHAPTER 2
SUMMARY OF THE REGULATION

The regulation affects sources using EO for commercial sterilization or fumigation operations. How a source is affected depends on the amount of EO that the source uses. In general, the regulation specifies:

- ✓ Compliance dates
- ✓ Emission reductions and limits
- ✓ Initial performance testing
- ✓ Ongoing monitoring
- ✓ Recordkeeping
- ✓ Reporting

Each of these requirements is summarized below. These requirements are discussed in more detail in subsequent chapters of this document. In addition, a detailed "table of contents" of the regulation is included in Appendix B of this document. It lists the requirements of the regulation and provides a cross-reference to the codified sections of the regulation where these requirements are found.

2.1 COMPLIANCE DATES[1]

All existing sources (i.e., initial startup date before December 8, 1997) that are subject to emissions standards (see section 2.2 below) must be in compliance with the regulation by December 6, 1997. All new sources (i.e., initial startup date after December 8, 1997) that are subject to emission standards must be in compliance with the regulation upon initial startup of the source.

[1]As of the publication date of this implementation document, the U. S. EPA is considering an extension of the compliance dates for these NESHAP. Readers are encouraged to consult future *Federal Register* notices for the latest compliance date information.

2.2 EMISSIONS REDUCTIONS AND LIMITS

The regulation specifies the following emission reductions and limits that depend on the piece of equipment and the amount of EO that the facility uses per year:

- ✓ For sterilization chamber vents (SCV's), at sources using 1 or more ton of EO per year, 99 percent reduction;
- ✓ For aeration room vents (ARV's) at sources using 10 or more tons of EO per year, 99 percent reduction OR 1 part per million by volume (ppmv) concentration limit; and
- ✓ For chamber exhaust vents (CEV's)/back draft vents at sources using 10 or more tons of EO per year, manifold to emission reduction device used to control SCV or ARV OR 99 percent reduction; for CEV's/back draft vents at sources using 1 to 10 tons of EO per year, 5,300 ppmv chamber concentration limit prior to activation of chamber exhaust.

2.3 INITIAL PERFORMANCE TESTING

Initial performance testing is required to demonstrate that the source is meeting the emissions standards. This is a one-time test. The regulation contains the test methods that will be used to determine initial compliance. During this initial performance test, the source will also establish operating parameter values that will be the bases for demonstrating ongoing compliance through monitoring of these parameters.

2.4 ONGOING MONITORING

Compliance with the regulation is demonstrated through ongoing monitoring of the operating parameter values established during initial testing. The monitoring requirements vary depending on the type of emission reduction technique the source uses. If using an acid-water scrubber, the source must monitor the ethylene glycol concentration or the scrubber liquor tank level once per week. If using a catalytic or thermal oxidation unit, the source must monitor the temperature continuously. For any type of emission reduction technique used to control emissions for ARV and for CEV (1 to 10 tons), the source may monitor the EO concentration once per hour for ARV and before activating the chamber exhaust for CEV.

2.5 RECORDKEEPING

The regulation requires that all sources keep records to document compliance with the regulation. Records for sources using 1 ton or more of EO per year include performance test results, monitoring and calibration data, and malfunctions and exceedances data. Records for sources using less than 1 ton of EO per year include annual usage data to demonstrate that they are not subject to the emission reduction requirements.

2.6 REPORTING

Reports for sources using 1 or more tons the EO per year include initial notification that the source is subject to the regulation, notification of performance tests and monitoring system evaluations, initial statement of compliance, and semi-annual compliance reports (on-going) containing information on the compliance status of the source.

CHAPTER 3
APPLICABILITY OF THE REGULATION

3.1 APPLICABILITY

The regulation applies to virtually all commercial sterilization and fumigation sources that use EO as a sterilant for heat and moisture sensitive products or as a fumigant to control microorganisms or insects, regardless of size (see exemptions listed in section 3.2). Both major and area sources are covered by the regulation. (Major sources are sources emitting 10 or more tons per year of any HAP or 25 or more tons per year of any combination of HAP's. Area sources, also referred to as "nonmajor sources," are sources that do not qualify as major.) The flowcharts in Figures 3-1 and 3-2 may be used to determine applicability of the requirements of the regulation to a particular source. Figure 3-1 highlights the requirements for sources using 1 to 10 tons of EO per year; Figure 3-2 highlights the requirements for sources using 10 tons or more of EO per year.

3.2 EXEMPTIONS

The regulation specifically exempts certain types of sources. These sources are:

- ✓ Beehive fumigators;
- ✓ Research and laboratory facilities, as defined in section 112(c)(7) of the CAA; and
- ✓ Medical facilities such as hospitals, doctors offices, clinics, or other facilities whose primary purpose is providing medical services to humans or animals.

3.3 SOURCE DESCRIPTION

The commercial sterilization source category covers the use of EO as a sterilant/fumigant in the production of medical equipment supplies and in miscellaneous sterilization and fumigation operations. Commercial sterilization facilities use EO as a sterilant for heat- or moisture-sensitive materials or as a fumigant to control microorganisms or insects. A variety of materials are sterilized or fumigated with EO, including medical equipment (e.g., syringes and surgical gloves), spices, cosmetics, and pharmaceuticals. Libraries and museums use EO to fumigate books and other historical items.

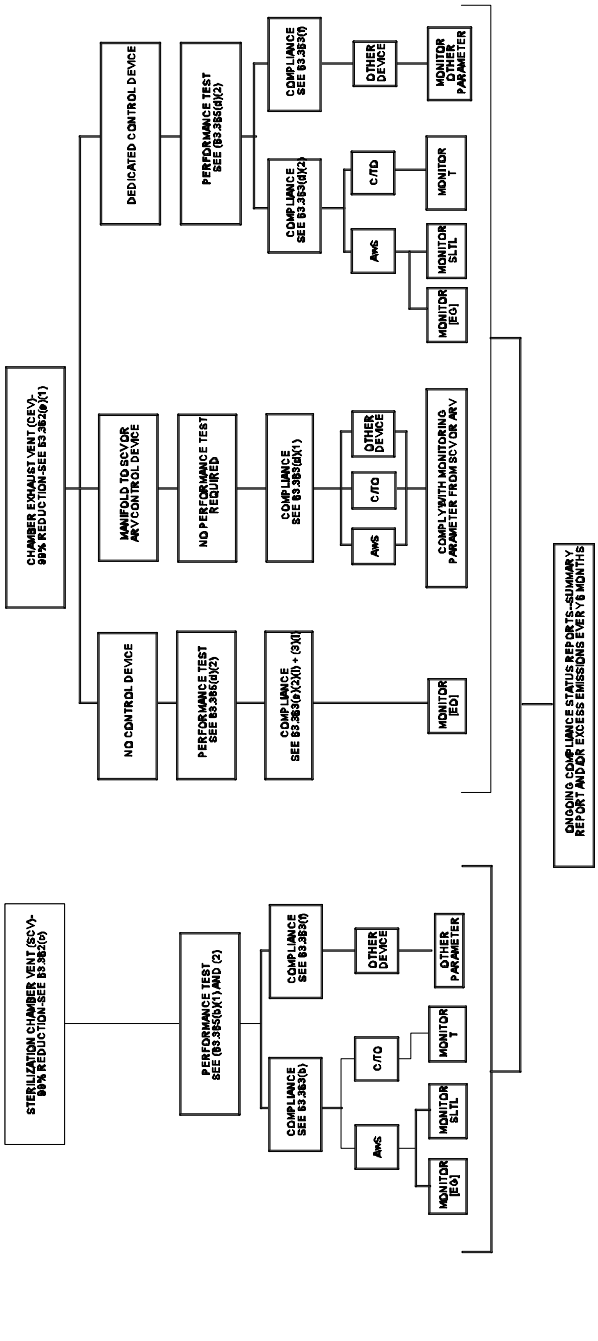

Figure 3-1. Applicability flowchart for sources using 1 to 10 tons of ethylene oxide per year.

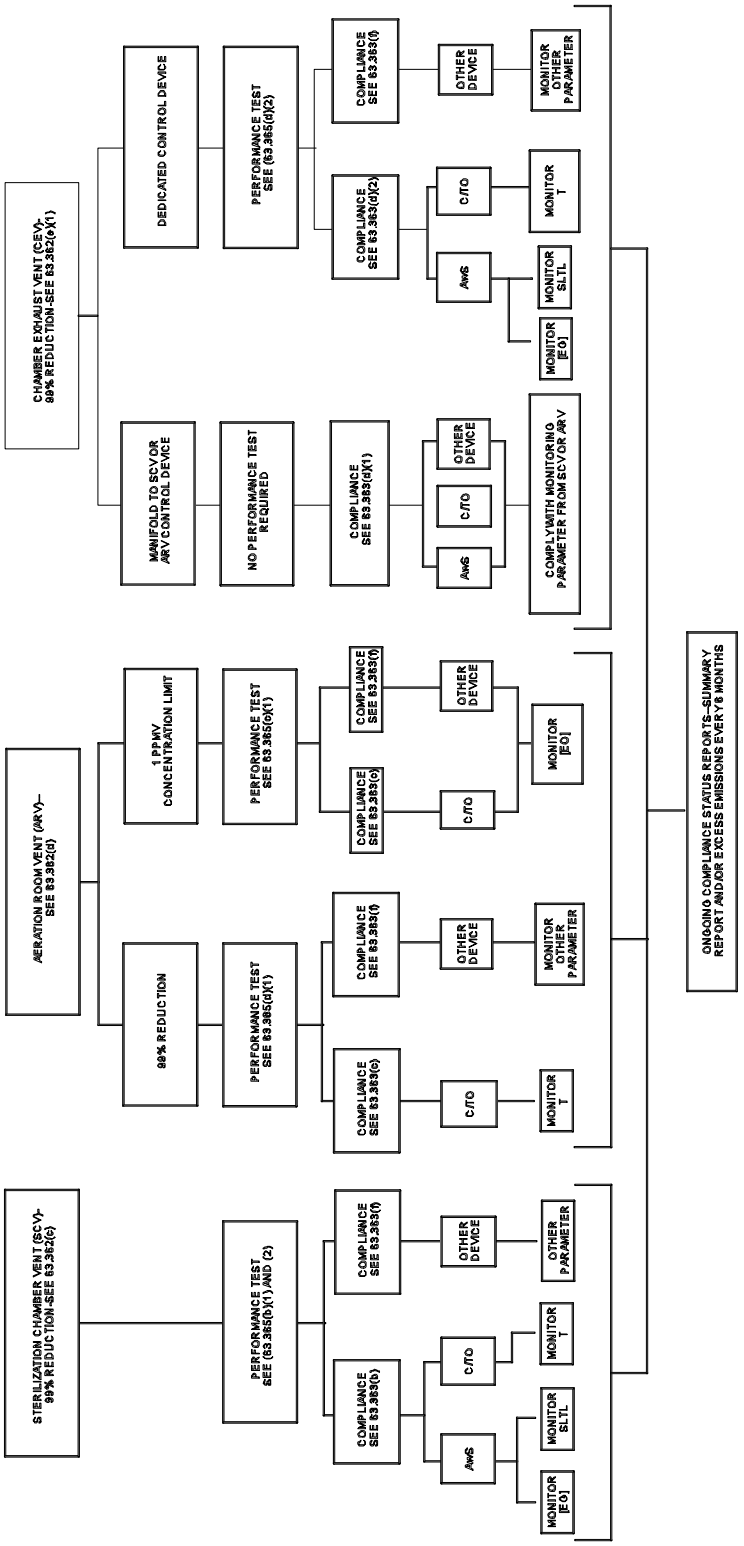

Figure 3-2. Applicability flowchart for sources using 10 tons or more of ethylene oxide per year.

There are two main types of EO sterilization processes: (1) bulk sterilization and (2) single-item sterilization. Using the single-item sterilization process, items are placed in a plastic pouch, sterilant gas is injected into the pouch, and the sealed pouch is placed into an aeration cabinet or room to allow sterilization to occur. Single-item sterilizers typically use much less than 1 ton of EO per year, and therefore, they may only be subject to minimal recordkeeping requirements of the NESHAP. Bulk sterilization is by far the more commonly used EO sterilization process. Using this process, products to be sterilized are placed in a sterilization chamber and are exposed to a sterilant gas at a predetermined temperature, humidity level, and pressure. The equipment, sterilant gases, and sterilization cycle used for bulk sterilization processes are described below.

3.3.1 Equipment

A schematic of a gas sterilizer is shown in Figure 3-3. The main components of the sterilizer are the chamber and vacuum pump. Chambers used by commercial sterilization facilities typically range in volume from 2.8 cubic meters (m^3) (100 cubic feet [ft^3]) to 28 m^3 (1,000 ft^3). A vacuum pump is used to remove air from the chamber before sterilization begins and to evacuate the sterilant gas after the sterilization cycle is complete.

3.3.2 Sterilant Gases

Ethylene oxide is an extremely effective sterilant gas. The EO penetrates product packaging (e.g., cardboard shipping box, plastic shrink wrap, paper box, and product wrapping) and destroys bacteria and viruses on the product. The product remains sterile until use because bacteria and viruses cannot penetrate the product wrapping. The most widely used sterilant gas is a mixture of 12 percent by weight EO and 88 percent by weight dichlorodifluoromethane (CFC-12), referred to as 12/88. Two other commonly used sterilant gases are (1) 100 percent pure EO and (2) a mixture of 10 percent by weight EO and 90 percent by weight carbon dioxide, referred to as 10/90.

3.3.3 Sterilization Cycle

The typical sterilization cycle consists of six phases: (1) presterilization conditioning, (2) sterilization, (3) evacuation, (4) air wash, (5) chamber exhaust, and (6) aeration. Each of these phases is discussed briefly below.

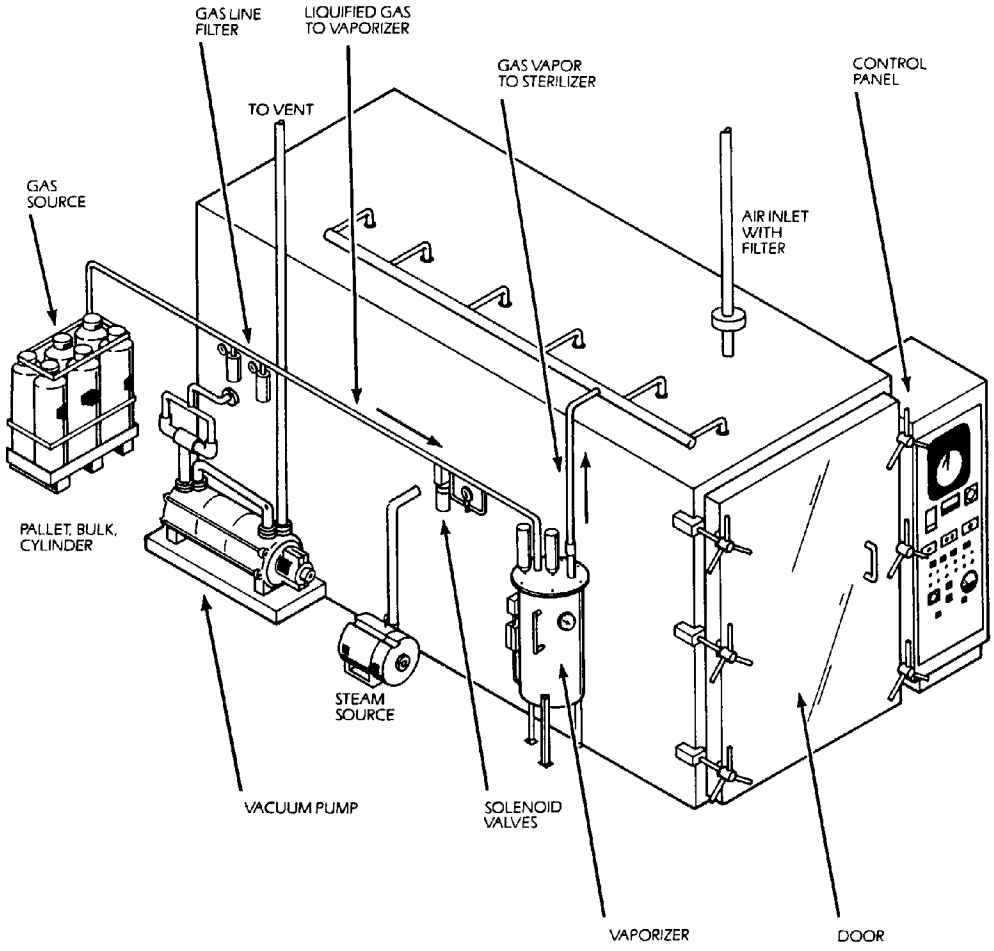

Figure 3-3. Schematic of a gas sterilizer.
(Courtesy of Union Carbide Corporation, Linde Division.)

3.3.3.1 Presterilization Conditioning. After the products have been loaded into the chamber and the airtight door is sealed, a partial vacuum is drawn inside the chamber. This initial vacuum, or drawdown, prevents dilution of the sterilant gas. Also, if flammable gas mixtures are used, the removal of air reduces the potential for ignition. The initial drawdown takes from about 5 to 45 minutes, depending on the product being sterilized. The chamber temperature is adjusted to ensure proper sterilization, and the relative humidity is raised to ensure susceptibility of microorganisms to the sterilant gas.

3.3.3.2 Sterilization. The sterilant, which is supplied as a liquid, is vaporized and introduced into the chamber to achieve the desired concentration of EO. The chamber pressure, which depends on the type of sterilant gas used, is maintained for about 4 to 6 hours.

3.3.3.3 Evacuation. Following sufficient exposure time, the sterilant gas is evacuated from the chamber with a vacuum pump. This postcycle vacuum phase typically lasts about 10 minutes.

3.3.3.4 Air Wash. The pressure in the chamber is bought to atmospheric pressure by introducing either air, nitrogen, or CO_2 (depending on the flammability of the sterilant gas mixture). The combination of evacuation and air wash phases is repeated from two to four times to remove as much of the EO from the product as possible. The purpose of the air washes is to allow residual EO to diffuse from the product to help meet Food and Drug Administration (FDA) guidelines on residual EO levels for medical devices, EPA residual tolerances for agricultural products, and the Occupational Safety and Health Administration (OSHA) standard for exposure in the workplace.

3.3.3.5 Chamber Exhaust. Prior to unloading the sterilizer, the chamber door is automatically cracked, and the chamber exhaust is activated. The chamber exhaust is an exhaust system that evacuates EO-laden air from the chamber prior to unloading and while the chamber is being unloaded (and reloaded). The chamber exhaust is a worker safety system that is responsible for removing EO from the void space in the sterilizer chamber. The chamber exhaust does not dramatically effect residual EO concentrations in the products being sterilized.

3.3.3.6 Aeration. Following their removal from the sterilization chamber, the sterile products are placed in an aeration room and kept there for several hours or days depending on the product. The purpose of aeration is to allow further diffusion of residual EO from the products prior to

shipping in order to comply with the FDA and EPA guidelines for residual EO. Ethylene oxide concentrations in the aeration room are maintained at relatively low levels by ventilating the room at a rate of about 20 air changes per hour. Also, aeration rooms are frequently heated to aid in EO offgasing.

3.3.4 Emission Sources

The four principal sources of EO emissions from sterilization/fumigation processes are the following:

- ✓ Sterilizer vent(s) (i.e., the vent on the vacuum pump gas/liquid separator);
- ✓ Sterilization chamber vacuum pump drain;
- ✓ Chamber exhaust vent(s); and
- ✓ Aeration room vent(s).

A schematic of these emission sources is shown in Figure 3-4.

3.4 NUMBER AND LOCATION OF AFFECTED SOURCES

Approximately 200 EO commercial sterilization and fumigation sources exist in the United States; approximately 150 of these sources are expected to be affected by the NESHAP. Table 3-1 lists the number of facilities by State according to EPA's data base compiled during the development of the NESHAP. Appendix C of this document lists the known facilities that are affected by this regulation.

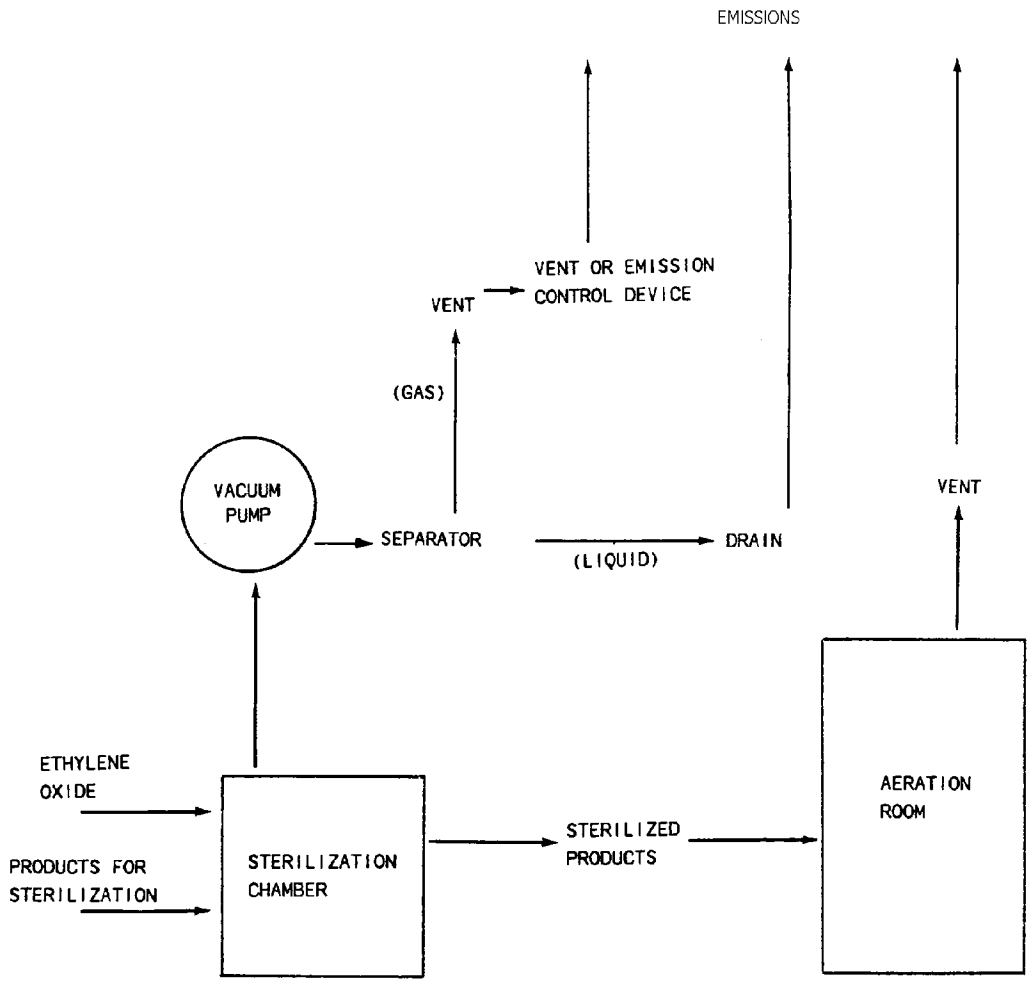

Figure 3-4. Schematic of emission sources at commercial sterilization facilities.

Table 3-1. Number of Facilities per State[a]

State	No. of facilities	State	No. of facilities
Arizona	3	Mississippi	2
Arkansas	2	Missouri	5
California	19	New Hampshire	2
Colorado	3	New Jersey	17
Connecticut	6	New York	13
Delaware	2	North Carolina	7
Florida	5	Ohio	2
Georgia	4	Pennsylvania	9
Illinois	8	Puerto Rico	14
Indiana	4	Rhode Island	2
Iowa	3	South Carolina	2
Maryland	5	Tennessee	3
Massachusetts	9	Texas	12
Michigan	8	Virginia	5
Minnesota	6	Washington	2
One facility is located in each of the following States: Alabama, Hawaii, Kentucky, Maine, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Utah, Wisconsin, and West Virginia.			
		Total No. of facilities	196

[a] Data base of facilities compiled by EPA during the development of the NESHAP.

CHAPTER 4
EMISSION LIMITS AND CONTROL TECHNIQUES

4.1 EMISSION LIMITS

The regulation specifies emissions standards as shown in Table 4-1 and provides reference emission reduction techniques that may be used to comply with the requirements. However, a source may use other emission reduction techniques, as long as the level of emission reduction is the same or better.

Table 4-1. Emissions Reductions and Limits

Source size, yearly EO usage	Emissions standards for each source type		
	Sterilization chamber vent, SCV	Aeration room vent, ARV	Chamber exhaust vent, CEV
<1 ton	No controls required; minimal recordkeeping requirements apply.		
≥1 ton and <10 tons	99% emission reduction	No control	Maximum chamber concentration limit of 5,300 ppmv prior to activation of the chamber exhaust [a]
≥10 tons	99% emission reduction	1 ppmv maximum outlet concentration --OR-- 99% emission reduction	Manifold to a control device used to comply with SCV or ARV standards --OR-- 99 percent emission reduction

[a]Affected sources may show compliance by manifolding emissions to a control device used to comply with the SCV or ARV standards by reducing emissions by at least 99 percent.

4.2 CONTROL TECHNIQUES

As mentioned above, the emission reductions and limits are based on the use of certain control techniques. However, a source may choose to use an alternative control technique, as long as the emission reductions and limits are met. The following paragraphs discuss the control techniques upon which the emissions limits found in Table 4.1 are based.

4.2.1 Acid-water Scrubber

An acid-water scrubber, depicted in Figure 4-1, consists of a countercurrent packed tower, a reaction vessel, and a holding tank. In the countercurrent tower, the sterilant gas contacts an

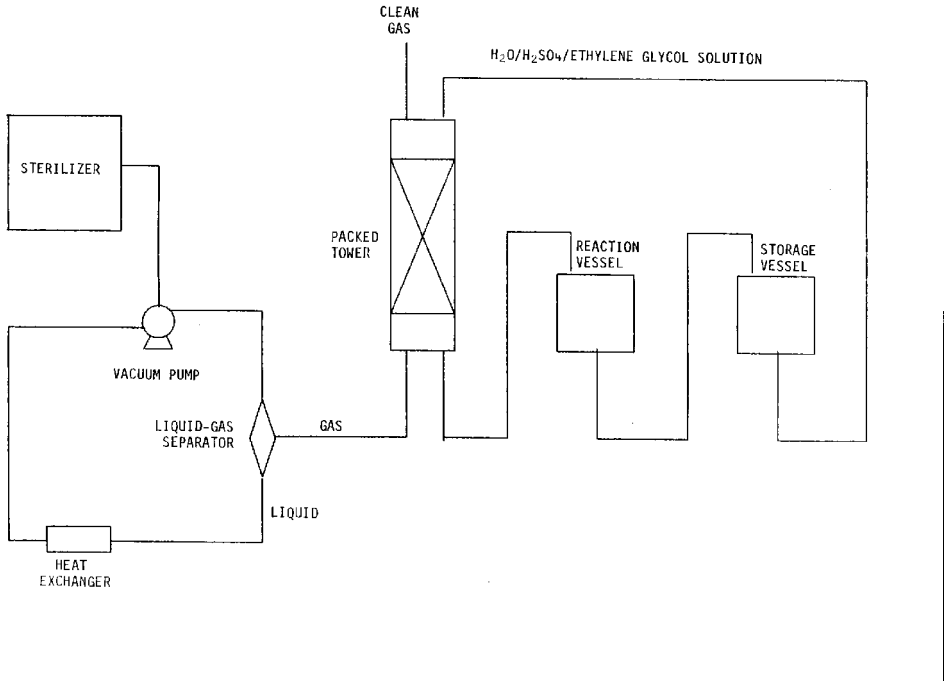

Figure 4-1. Schematic of a typical acid water scrubber system.

acidic water solution, generally aqueous sulfuric acid. Because EO is extremely water soluble, most of the EO is absorbed into the scrubber liquor. Next, the liquor is sent to the reaction vessel, which is a small storage tank operated at atmospheric pressure, to complete the hydrolysis of EO. After the reaction is complete, the liquor is sent to the storage vessel. The liquor in the storage vessel is recirculated to operate the tower until the concentration of ethylene glycol in the liquor reaches a predetermined weight percentage. (At this point the scrubber efficiency declines.) The spent solution is neutralized and then disposed or sold. Typical EO removal efficiencies of acid-water scrubbers are at least 99 percent.

4.2.2 Catalytic Oxidation Unit

Figure 4-2 shows a schematic of a catalytic oxidation unit. If necessary, inlet gas is first mixed with a large volume of air to dilute the control device inlet EO concentration to 5,000 ppmv or less. This dilution prevents excessive catalyst bed temperatures (which can damage the catalyst) from occurring during the oxidation of EO. The gas stream passes through a filter for dust removal and is preheated to the reaction temperature with steam or electricity.

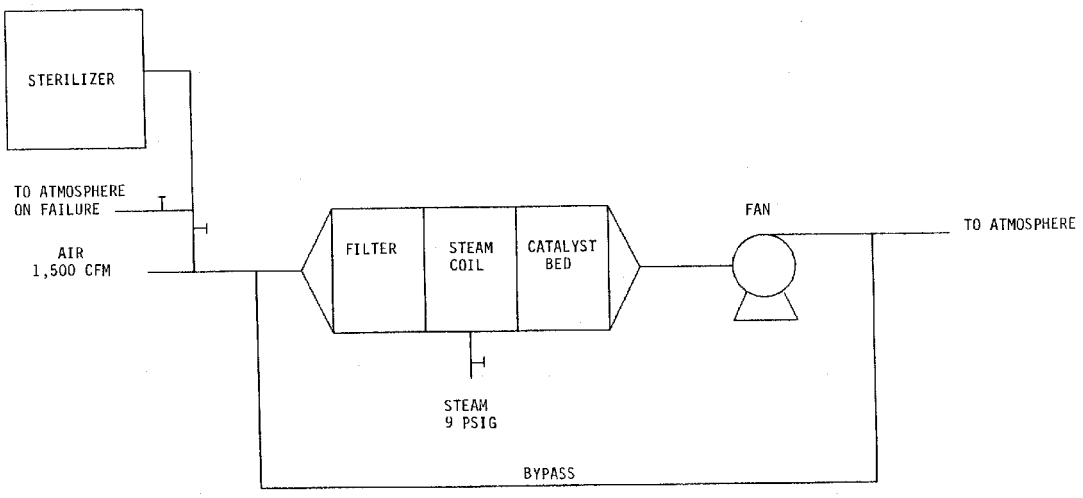

Figure 4-2. Catalytic oxidation system.

The gas then enters the catalyst bed(s), where the EO is oxidized. Because catalytic oxidation is applicable to the control of lower EO concentrations, facilities can manifold several EO emission sources to one control device. In some situations, low-concentration emission sources can provide part or all of the necessary diluent air. Typical EO removal efficiencies of catalytic oxidation units are greater than 99 percent.

4.2.3 Thermal Oxidation Unit

A thermal oxidation unit is depicted in Figure 4-3. Ethylene oxide, which has a high heating value, a relatively low ignition temperature, and a very wide range of mixtures combustible in air, can be easily and efficiently destroyed by thermal oxidation using flares. However, because of difficulties with sustaining combustion, commercially available flares are not applicable for facilities emitting only small amounts of EO. Flares operated within specified conditions of waste gas heat content and flare exit velocity will achieve at least 98 percent EO destruction efficiency.

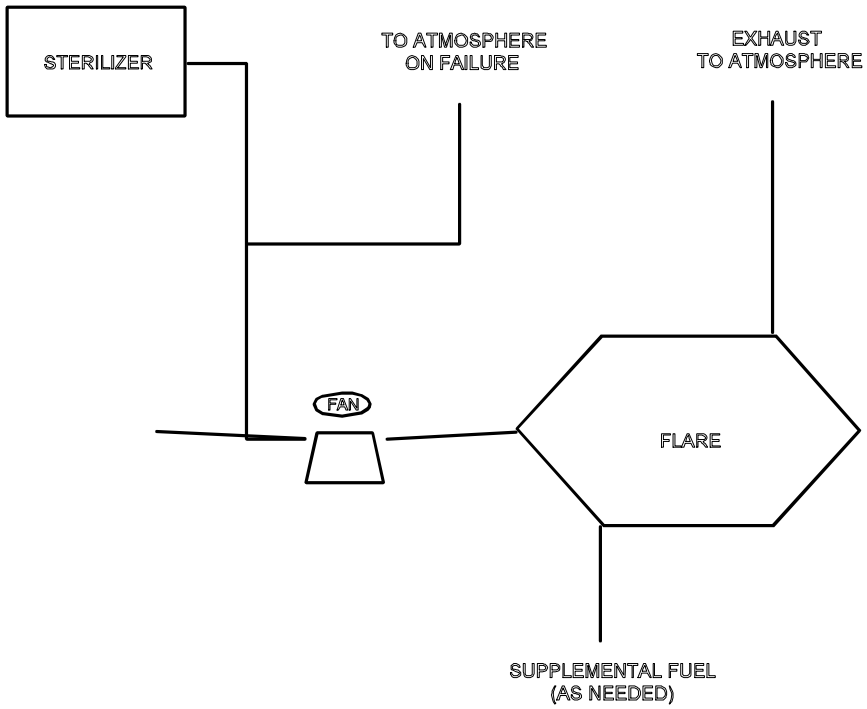

Figure 4-3. Schematic of a typical thermal oxidation system.

CHAPTER 5
DEMONSTRATING COMPLIANCE

There are three components to demonstrating compliance with the emissions standards of this regulation:

- ✓ Initial performance testing
- ✓ Site-specific operating parameters setting
- ✓ Ongoing compliance monitoring

5.1 INITIAL PERFORMANCE TESTING

The initial performance test serves two primary purposes. First, it is necessary to determine if the source is in compliance with the emissions standards listed in Table 4-1 of this document. Second, the initial performance test establishes values for the air pollution control system operating parameters. Monitoring and recording these operating parameters during ongoing sterilization processes will indicate whether or not the source is in compliance with the emissions standards.

Each existing source that is subject to emissions standards is required to perform an initial performance test by June 4, 1998. For sources with an initial startup date of December 8, 1997 or later, the initial performance test must be completed within 180 days after initial startup. Section 63.365 of the regulation specifies test methods and procedures to be used to determine the efficiency of the control devices.

5.2 ESTABLISHING SITE-SPECIFIC OPERATING PARAMETERS

During initial performance testing, applicable air pollution control technique operating parameters must be recorded. These site-specific operating parameters are determined by the air pollution control technique or strategy that the source is using and are listed in Table 5-1. Table 5-1 also refers to the location in the NESHAP for the procedure to be used to establish the site-specific operating parameter.

If a facility chooses to use a control technology other than an acid-water scrubber or catalytic or thermal oxidizer to comply with the emissions standards, the owner or operator of the facility must submit to the appropriate enforcement agency their own recommendations for operating

Table 5-1. Site-specific Operating Parameters

Air pollution control system or strategy	Site-specific operating parameter	Procedure in regulation
Sterilization Chamber Vent (SCV) Standard		
Acid-water scrubber	1. Maximum ethylene glycol concentration in scrubber liquor --OR--	§ 63.365(e)(1)
	2. Maximum scrubber liquor level in recirculation tank	§ 63.365(e)(2)
Catalytic or thermal oxidizer	Baseline temperature during initial performance test	§ 63.365(f)(1)
Aeration Room Vent (ARV) Standard		
Catalytic or thermal oxidizer	Baseline temperature during initial performance test	§ 63.365(f)(2)
Chamber Exhaust Vent (CEV) Standard		
Manifolding emissions to a control device controlling emissions from the SCV and/or the ARV	See appropriate columns above for that vent type and control device	See appropriate columns above.
Not manifolding emissions and using an acid-water scrubber	1. Maximum ethylene glycol concentration in scrubber liquor --OR--	§ 63.365(e)(1)
	2. Maximum scrubber liquor level in recirculation tank	§ 63.365(e)(2)
Not manifolding emissions and using a catalytic or thermal oxidizer	Baseline temperature during initial performance test	§ 63.365(f)(3)

parameters to be established and monitored to indicate proper operation and maintenance of their air pollution control system.

5.3 ONGOING MONITORING

During performance testing, site-specific operating parameters are established, as discussed above. Facilities must continue to monitor these operating parameters to ensure ongoing continuous compliance with the emissions standards. By monitoring and recording the appropriate air pollution control system parameters and comparing the monitored values to the maximum or minimum value established during the performance test, the enforcing agency can determine if the facility is in compliance with the emissions standards. Tables 5-2, 5-3, and 5-4 summarize the ongoing monitoring requirements associated with the sterilization chamber vent standard, aeration room vent standard, and the chamber exhaust vent standard, respectively. Each of these tables includes the equipment specifications and the monitoring frequency, as well as indicators of a violation of the standard for the various air pollution control systems and strategies that may be used.

Table 5-2. Summary of Ongoing Monitoring Requirements for the Sterilization Chamber Vent Standard

Air pollution control system or strategy	Monitored parameter	Monitoring equipment	Frequency	Violation
Acid-water scrubber	1. Ethylene glycol concentration in scrubber liquor --OR--		Once per week [a]	Exceedance of maximum ethylene glycol concentration in scrubber liquor established during initial performance test
	2. Scrubber liquor level in recirculation tank	Liquid level indicator (e.g., marker on tank wall, dipstick, magnetic indicator)	Once per week	Exceedance of maximum scrubber liquor level established during initial performance test
Catalytic or thermal oxidizer	Oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber	1. Temperature monitor accurate to within ±10°F [b] --AND--	Continuously	Oxidation temperature, averaged over 3 cycles, more than 10°F below baseline temperature established during initial performance test
		2. Data acquisition system [c]		

[a]Monitoring is only required during weeks when the scrubber unit has been operated.

[b]Accuracy of temperature monitor must be verified twice each calendar year using a reference temperature monitor.

[c]The data acquisition system must compute and record the average oxidation temperature over the length of the sterilization cycle (based on the length of cycle used during the performance test) and a three-cycle block average every third cycle.

Table 5-3. Summary of Ongoing Monitoring Requirements for the Aeration Room Vent Standard

Air pollution control system or strategy	Monitored oarameter	Monitoring equipment	Frequency	Violation
Catalytic or thermal oxidizer	Oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber	1. Temperature monitor accurate to within ±10°F [a] --AND-- 2. Data acquisition system [b]	Continuously	Oxidation temperature, averaged over 3 hours, more than 10°F below baseline temperature established during initial performance test
Direct measurement of EO concentration	EO concentration at outlet to atmosphere from ARV after any control device	Gas chromatograph [c]	Once per hour and compute 3-hour average every third hour	3-hour average EO concentration in excess of 1 ppmv EO concentration limit

[a] Accuracy of temperature monitor must be verified twice each calendar year using a reference temperature monitor.

[b] The data acquisition system must compute and record the average oxidation temperature each hour and a 3-hour block average every third hour.

[c] Facility must install, calibrate, operate, and maintain gas chromatograph consistent with performance specification 9 in 40 CFR part 60, Appendix B. Daily calibration is only required on days when EO emissions are vented to a control device from the ARV.

Table 5-4. Summary of Ongoing Monitoring Requirements for the Chamber Exhaust Vent Standard

Air pollution control system or strategy	Monitored parameter	Monitoring equipment	Frequency	Violation
Not manifolding emissions and using an acid-water scrubber	1. Ethylene glycol concentration in scrubber liquor --OR--	N/A?	Once per week [a]	Exceedance of maximum ethylene glycol concentration in scrubber liquor established during initial performance test
	2. Scrubber liquor level in recirculation tank	Liquid level indicator (e.g., marker on tank wall, dipstick, magnetic indicator)	Once per week	Exceedance of maximum scrubber liquor level established during initial performance test
Not manifolding emissions and using a catalytic or thermal oxidizer	Oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber	1. Temperature monitor accurate to within ±10 °F [b] --AND--	Continuously	Oxidation temperature, averaged over cycle, more than 10°F below baseline established during initial performance test
		2. Data acquisition system[c]		
Direct measurement of EO concentration	EO concentration in sterilization chamber immediately before chamber exhaust is activated	Gas chromatograph[d]	Before chamber exhaust is activated	Exceedance of 5,300 ppmv EO concentration standard
Manifolding emissions to a control device controlling emissions from the SCV and/or the ARV	See appropriate columns in Tables 5-2 and 5-3 for that vent type and control device			

[a] Monitoring is only required during weeks when the scrubber unit has been operated.

[b] Accuracy of temperature monitor must be verified twice each calendar year using a reference temperature monitor.

[c] The data acquisition system must compute and record the average oxidation temperature over the length of the sterilization cycle (based on the length of cycle used during the initial performance test).

[d] Facility must install, calibrate, operate, and maintain gas chromatograph consistent with Performance Specification 9 in 40 CFR Part 60, Appendix B. Daily calibration is only required on days when the chamber exhaust is activated.

CHAPTER 6
RECORDKEEPING AND REPORTING REQUIREMENTS

Most of the recordkeeping and reporting requirements are not detailed in the NESHAP. Instead, they are contained in the General Provisions to part 63 and simply referenced in Table 1 of Section 63.360 in the NESHAP. This table provides specific references to those sections of the General Provisions that apply to the commercial sterilization and fumigation NESHAP. The EPA chose to reference the recordkeeping and reporting requirements of the General Provisions to help reduce unnecessary repetitiveness, and to help provide consistency between the different NESHAP in part 63.

6.1 RECORDKEEPING

The regulation requires sources to keep records to document compliance status with the regulation. These records include:

- ✓ Malfunction records
- ✓ Records to demonstrate compliance
- ✓ Performance test results
- ✓ Continuous monitoring system records
- ✓ Documentation supporting initial notification and notification of compliance status
- ✓ EO usage records for sources not subject to emissions standards

These records must be maintained in a form suitable and readily available for expeditious inspection and review. They may be maintained on microfilm, computer, computer floppy disks, magnetic tape disks, or microfiche. The files must be retained for at least 5 years, and the most recent 2 years of data must be retained on site.

6.1.1 Malfunction Records

Sources must maintain records of the occurrence and duration of each malfunction of the air pollution control equipment. Records of each period during which a CMS is malfunctioning or inoperative (including out-of-control periods) are also required.

6.1.2 Records to Demonstrate Compliance

Sources are also required to maintain records of all required measurements needed to demonstrate compliance with the standard. These records should include the data compiled

according to Tables 5-2, 5-3 and 5-4 of this document, which detail the monitoring requirements of the NESHAP.

6.1.3 Performance Test Results

Sources must maintain records of all results of performance tests and CMS performance evaluations, as well as all measurements necessary to determine the conditions of performance tests and performance evaluations.

6.1.4 Continuous Monitoring System Records

Records relating to CMS must include: (1) all CMS calibration checks; (2) all adjustments and maintenance performed on CMS; (3) all required CMS measurements (including monitoring data recorded during unavoidable CMS breakdowns and out-of-control periods); (4) the date and time identifying each period during which the CMS was inoperative except for zero (low-level) and high-level checks; (5) the specific identification (i.e., the date and time of commencement and completion) of each time period of excess emissions and parameter monitoring exceedances that occurs during periods other than startups, shutdowns, and malfunctions of the source; (6) the nature and cause of any malfunction (if known); the corrective action taken or preventive measures adopted; (7) the nature of the repairs or adjustment to the CMS that was inoperative or out of control; (8) the total process operating time during the reporting period; and (9) all procedures that are part of a quality control program developed and implemented for CMS.

6.1.5 Documentation Supporting Initial Notification and Notification of Compliance Status

Sources are required to maintain all documentation supporting the initial notifications and notifications of compliance status required by the NESHAP.

6.1.6 Records for Sources Not Subject to Emissions Standards

Sources that use 1 to 10 tons of EO per year and that are not subject to emissions standards (see Table 4-1 of this document) are only required to keep records of EO usage on a 12-month rolling basis. Sources that use less than 1 ton of EO per year are also only required to keep EO usage records on a 12-month rolling basis.

6.2 REPORTING

The regulation requires that sources submit reports and notifications, which include:

- ✓ Initial notification
- ✓ Notification of construction/reconstruction
- ✓ Notification of performance test and CMS performance evaluation
- ✓ Test plans (to be submitted upon request)
- ✓ Notification of compliance status
- ✓ Excess emission and CMS performance report/summary report

All reports must be submitted to the Administrator (i.e., the appropriate EPA Regional Office or the delegated State or local authority). The required reports may be sent by U. S. Mail, fax, or by another courier (including electronic submission).

6.2.1 Initial Notification

Sources with an initial startup date before December 6, 1994 were required to submit an initial notification to the Administrator on or before April 5, 1995 (120 days after the effective date of the standards). New or reconstructed sources with an initial startup date after December 6, 1994 are required to submit an initial notification within 120 calendar days after the source becomes subject to the standards. The initial notification includes the following information: (1) the name and address of the owner or operator; (2) the physical address of the source; (3) an identification of the relevant standard or other requirement and the source's compliance date; (4) a brief description of the nature, size, design, and method of operation of the source; and (5) a statement of whether the source is a major source or an area source.

6.2.2 Notification of Construction/Reconstruction[2]

Sources must apply for approval of the construction of a new affected source. Sources must also apply prior to the reconstruction of a nonaffected source if the reconstruction would result in

[2]The construction/reconstruction requirements of the General Provisions to Part 63 (Subpart A) are undergoing revisions as of the publication date of this implementation document. Readers are encouraged to consult future *Federal Register* notices for the latest construction/ reconstruction information.

the source being an affected source. All applications must be submitted to the Administrator as soon as practicable to ensure timely review.

6.2.3 Notification of Performance Test and CMS Performance Evaluation

Sources must notify the Administrator in writing of intent to conduct an initial performance test at least 60 calendar days before the scheduled date of the test to allow the Administrator to review and approve their site-specific test plan and to have an observer present at the test. Simultaneously with this notification, the source will also notify the Administrator of the date of the continuous monitoring system (CMS) performance evaluation. The Administrator may or may not choose to have an observer present. If the scheduled date for the test is changed for unforeseen reasons, the source will inform the Administrator within 5 calendar days of the originally scheduled test date and will specify the date of the rescheduled test.

6.2.4 Test Plans

Before conducting the initial performance test, sources are required to develop and, if requested by the Administrator, submit a site-specific test plan and a CMS performance evaluation test plan to the Administrator for approval. The test plan will include: (1) a test program summary, (2) the test schedule, (3) data quality objectives (i.e., pretest expectations of precision, accuracy, and completeness of data), (4) an internal and external quality assurance (QA) program. The CMS performance evaluation test plan will include: (1) the evaluation program summary, (2) the performance evaluation schedule, (3) data quality objectives, and (4) both an internal an external QA program. If requested by the Administrator, the source will submit these test plans at least 60 calendar days before the performance test is scheduled to take place. The Administrator will then either approve or disapprove the test plans within 30 calendar days after receipt of the plans.

6.2.5 Notification of Compliance Status

Sources are required to submit a notification of compliance status within 60 days after the initial performance test. The notification must include: (1) the methods that were used to determine compliance; (2) the results of the performance test and the CMS performance evaluation; (3) the methods that will be used for determining continuing compliance; (4) the type and quality of HAPs emitted, reported in units and averaging times specified in the regulation; (5)

an analysis demonstrating whether the source is a major source or an area source; (6) a description of the air pollution control equipment (or method) for each emission point, including the control efficiency for each control device (or method); and (7) a statement as to whether the source has complied with the relevant standard or other requirements.

6.2.6 Excess Emissions and CMS Performance Report/Summary Report

Sources are required to submit an excess emissions and CMS performance report and/or a summary report to the Administrator semiannually. These reports are due 30 calendar days after each half of the calendar year (i.e., July 30 and January 30). A summary report may be submitted in lieu of the full excess emissions and CMS performance report if the total duration of excess emissions or process or control system parameter exceedances for the reporting period is less than 1 percent of the total operating time for the reporting period, and if the CMS downtime of the reporting period is less than 5 percent of the total operating time for the reporting period. Otherwise, the summary report and the excess emissions and CMS performance report is required.

The summary report must include: (1) the company name and address of the source; (2) an identification of each HAP monitored at the source; (3) the beginning and ending dates of the reporting period; (4) a brief description of the process units; (5) the relevant emission and operating parameter limitations specified in the NESHAP; (6) the monitoring equipment and manufacturer(s) and model number(s); (7) the date of the latest CMS certification or audit; (8) the total operating time of the source during the reporting period; (8) an emission data summary, including the total duration of excess emissions during the reporting period, the total during of excess emissions expressed as a percent of the total source operating time during that reporting period;, and a breakdown of the total duration of excess emissions during the reporting period into those that are due to startup/shutdown, control equipment problems, process problems, other known causes, and other unknown causes; (9) a CMS performance summary, including the total CMS down time during the reporting period, the total duration of CMS downtime expressed as a percent of the total source operating time during that reporting period, and a breakdown of the total CMS downtime during the reporting period into periods that are due to monitoring equipment malfunctions, nonmonitoring equipment malfunctions, quality assurance/quality control

calibration, other known causes, and other unknown causes; (10) a description of any changes in CMS, processes, or controls since the last reporting period; (11) the name, title, and signature of the responsible official who is certifying the accuracy of the report; and (12) the date of the report.

The excess emissions and CMS performance report must include: (1) the name, title, and signature of the responsible official who is certifying the accuracy of the report; (2) information from any calibration tests in which the monitoring equipment is not in compliance with performance specification (PS) -9 of 40 CFR part 60 or the method used for temperature calibration; (3) the date and time identifying each period during which the CMS was inoperative, except for zero (low-level) and high-level checks; (4) the date and time identifying each period during which the CMS was out of control; (5) the date and time of commencement and completion of each period of excess emissions and parameter monitoring exceedances that occurs during startups, shutdowns, and malfunction of the source; (6) the date and time of commencement and completion of each period of excess emissions and parameter monitoring exceedances that occurs during periods other than startups, shutdowns, and malfunctions of the source; (7) the nature and cause of any malfunction (if known); (8) the corrective action taken or preventive measures adopted; (9) the nature of the repairs or adjustment to the CMS that was inoperative or out of control; and (10) the total process operating time during the reporting period. When no excess emissions or exceedances have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information should be stated in the report.

CHAPTER 7
INSPECTION PROCEDURES

The following comprise sample checklists that may be used during inspections of affected sources.

INSPECTION CHECKLIST

PART A. GENERAL PROCESS INFORMATION

Applicable Rule: 40 CFR Part 63, Subpart O—NESHAP for Ethylene Oxide Commercial Sterilization and Fumigation Operations.

Plant Name _____

Plant Address _____

_____

City_____ State_____ Zip Code_____

Plant Contact/Title_____Plant Phone number _____

Owner/Operator, Title_____

Street Address (if different than plant's)_____

_____

City_____ Sate_____ Zip Code _____

1. Inspection Date: ___/___/___ Time:_____
2. Indicate whether a facility is a new or existing source:

   ___ New source ___ Existing source
3. Indicate the facility's compliance date: ___/___/___
4. Indicate the facility's annual EO use in previous 12 months: _____
5. Indicate the facility's compliance approach

   Sterilization chamber vent:

   ___ Acid-Water scrubber ___ Oxidizer ___ Other (_____)

   Chamber exhaust vent:

   ___ 5,300 ppm limit ___ Manifolded to control device ___ Dedicated control device

   ___ Acid-Water scrubber ___ Oxidizer ___ Other (_____)

   Aeration room vent:

   ___ 1 ppm max ___ Manifolded to control device ___ Dedicated control device

   ___ Acid-Water scrubber ___ Oxidizer ___ Other (_____)

Investigator/Title:_____Date:___/___/___

INSPECTION CHECKLIST

PART B. MONITORING REQUIREMENTS FOR STERILIZATION CHAMBER VENTS

Inspection steps	Value	Y	N	Inspector notes
General				
1. From Part A of the Inspection Checklist, determine the dedicated control device used to comply with the standard.				
2. Determine that source has complied with the requirements for the appropriate dedicated control device; follow the inspection steps listed on the appropriate forms:				

Inspection steps	Value	Y	N	Inspector notes
Acid-Water Scrubbers				
1. Enter the site-specific operating parameter value established during the initial performance test (i.e., either the maximum ethylene glycol concentration in the scrubber liquor or the maximum scrubber liquor level in the recirculation tank).				
2. Obtain records of ongoing monitoring data.				
3. Answer (a) or (b): (a) Has the ethylene glycol concentration in the scrubber liquor been monitored and recorded once per week? (b) Has the scrubber liquor level in the recirculation tank been monitored and recorded once per week?				
4. Answer (a) or (b): (a) Has the source exceeded the maximum ethylene glycol concentration in the scrubber liquor established during the initial performance test? (b) Has the source exceeded the maximum scrubber liquor level established during the initial performance test?				
5. If the answer to step 4 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

Inspection steps	Value	Y	N	Inspector notes
Thermal or Catalytic Oxidizers				
1. Obtain and enter the site-specific operating parameter value established during the initial performance test (i.e., oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber).				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a temperature monitor accurate to within ±10°F as verified twice each calendar year with a reference temperature monitor?				
4. Does the source operate a data acquisition system that computes and records the average oxidation temperature over the length of the cycle and a three-cycle block average every third cycle?				
5. Has the oxidation temperature, averaged over 3 cycles, been more than 10°F below the baseline temperature established during the initial performance test?				
6. If the answer to step 5 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

Inspection steps	Value	Y	N	Inspector notes
Other Control Devices				
1. Enter the site-specific operating parameter value established during the initial performance test.				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a monitoring device(s) accurate to within the tolerances in the site specific monitoring plan approved by the Administrator and verified in accordance with this plan?				
4. Does the source operate a data acquisition system that computes and records a monitoring parameter(s) according to the schedule specified in the site specific monitoring plan approved by the Administrator?				
5. Have the recorded values shown violation of the parameters?				
6. If the answer to step 5 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

INSPECTION CHECKLIST

PART C. MONITORING REQUIREMENTS FOR CHAMBER EXHAUST VENTS

Step in inspection	Value	Y	N	Inspector notes
General				
1. From Part A of the Inspection Checklist, determine the method of compliance: (a) Monitor EO concentration. Go to Step 2. (b) Manifold emissions to control device. Go to Step 5. (c) Emissions controlled via dedicated control device. Go to Step 6.				
2. Obtain records of ongoing monitoring data.				
3. Has the ethylene oxide concentration exceeded the 5,300 ppm limit?				
4. If the answer to step 3 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				
5. Determine that source has complied with the requirements for that control device on that emissions point (continue on Part B, or Part D as appropriate).				
6. Determine that source has complied with the requirements for the appropriate dedicated control device as follows:				

Step in inspection	Value	Y	N	Inspector notes
Acid-Water Scrubbers				
1. Enter the site-specific operating parameter value established during the initial performance test (i.e., either the maximum ethylene glycol concentration in the scrubber liquor or the maximum scrubber liquor level in the recirculation tank).				
2. Obtain records of ongoing monitoring data.				
3. Answer (a) or (b): (a) Has the ethylene glycol concentration in the scrubber liquor been monitored and recorded once per week? (b) Has the scrubber liquor level in the recirculation tank been monitored and recorded once per week?				
4. Answer (a) or (b): (a) Has the source exceeded the maximum ethylene glycol concentration in the scrubber liquor established during the initial performance test? (b) Has the source exceeded the maximum scrubber liquor level established during the initial performance test?				
5. If the answer to step 4 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

RECORDING AND REPORTING REQUIREMENTS

Step in inspection	Value	Y	N	Inspector notes
Thermal or Catalytic Oxidizers				
1. Enter the site-specific operating parameter value established during the initial performance test (i.e., oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber).				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a temperature monitor accurate to within ±10°F as verified twice each calendar year with a reference temperature monitor?				
4. Does the source operate a data acquisition system that computes and records the average oxidation temperature over the length of the cycle and a three-cycle block average every third cycle?				
5. Has the oxidation temperature, averaged over 3 cycles, been more than 10°F below the baseline temperature established during the initial performance test?				
6. If the answer to step 5 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

Step in inspection	Value	Y	N	Inspector notes
Other Control Devices				
1. Enter the site-specific operating parameter value established during the initial performance test.				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a monitoring device(s) accurate to within the tolerances in the site specific monitoring plan approved by the Administrator and verified in accordance with this plan?				
4. Does the source operate a data acquisition system that computes and records a monitoring parameter(s) according to the schedule specified in the site specific monitoring plan approved by the Administrator?				
5. Have the recorded values shown violation of the parameters?				
6. If the answer to step 5 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

INSPECTION CHECKLIST

PART D. MONITORING REQUIREMENTS FOR AERATION ROOM VENTS

Step in inspection	Value	Y	N	Inspector notes
General				
1. From Part A of the Inspection Checklist, determine the method of compliance: (a) Monitor EO concentration. Go to Step 2. (b) Manifold emissions to control device. Go to Step 5. (c) Emissions controlled via dedicated control device. Go to Step 6.				
2. Obtain records of ongoing monitoring data.				
3. Has the ethylene oxide concentration exceeded the 1 ppm limit?				
4. If the answer to step 3 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				
5. Determine that source has complied with the requirements for that control device on that emissions point (continue on Part B, or Part D as appropriate).				
6. Determine that source has complied with the requirements for the appropriate device as follows:				

Step in inspection	Value	Y	N	Inspector notes
Acid-Water Scrubbers				
1. Enter the site-specific operating parameter value established during the initial performance test (i.e., either the maximum ethylene glycol concentration in the scrubber liquor or the maximum scrubber liquor level in the recirculation tank).				
2. Obtain records of ongoing monitoring data.				
3. Answer (a) or (b): (a) Has the ethylene glycol concentration in the scrubber liquor been monitored and recorded once per week? (b) Has the scrubber liquor level in the recirculation tank been monitored and recorded once per week?				
4. Answer (a) or (b): (a) Has the source exceeded the maximum ethylene glycol concentration in the scrubber liquor established during the initial performance test? (b) Has the source exceeded the maximum scrubber liquor level established during the initial performance test?				
5. If the answer to step 4 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

RECORDING AND REPORTING REQUIREMENTS

Step in inspection	Value	Y	N	Inspector notes
Thermal or Catalytic Oxidizers				
1. Enter the site-specific operating parameter value established during the initial performance test (i.e., oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber).				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a temperature monitor accurate to within ±10°F as verified twice each calendar year with a reference temperature monitor?				
4. Does the source operate a data acquisition system that computes and records the average oxidation temperature over the length of the cycle and a three-cycle block average every third cycle?				
5. Has the oxidation temperature, averaged over 3 cycles, been more than 10°F below the baseline temperature established during the initial performance test?				
6. If the answer to step 5 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

Step in inspection	Value	Y	N	Inspector notes
Other Control Devices				
1. Enter the site-specific operating parameter value established during the initial performance test.				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a monitoring device(s) accurate to within the tolerances in the site specific monitoring plan approved by the Administrator and verified in accordance with this plan?				
4. Does the source operate a data acquisition system that computes and records a monitoring parameter(s) according to the schedule specified in the site specific monitoring plan approved by the Administrator?				
5. Have the recorded values shown violation of the parameters?				
6. If the answer to step 5 is “Yes,” has the source reported the excess emissions to the Administrator? Stop here.				

INSPECTION CHECKLIST

PART D. RECORDKEEPING REQUIREMENTS

Step in inspection	Y	N	Inspector notes
1. Does the source use less than 10 tons of ethylene oxide per year? If "Yes," go to Step 2. If "No," go to Step 4.			
2. Is the source subject to emissions limitations in the regulation? If "Yes," go to Step 4. If "No," go to Step 3.			
3. Does the source maintain records of EO usage on a 12-month rolling basis? Stop here.			
4. Does the source maintain the following malfunction records: (a) The occurrence and duration of each malfunction of the air pollution control equipment; AND (b) Records of each period during which a continuous monitoring system is malfunctioning or inoperative (including out-of-control periods)?			
5. Does the source maintain records of all required measurements needed to demonstrate compliance with the standard?			
6. Does the source maintain records of all results of performance tests and CMS performance evaluations, as well as all measurements as may be necessary to determine the conditions of the performance tests and evaluations?			

RECORDING AND REPORTING REQUIREMENTS

Step in inspection	Y	N	Inspector notes
7. Does the source maintain the following records relating to CMS: (a) All CMS calibration checks; (b) All adjustments and maintenance performed on CMS; (c) All required CMS measurements (including monitoring data recorded during unavoidable CMS breakdowns and out-of-control periods); (d) The date and time identifying each period during which the CMS was inoperative except for zero (low-level) and high-level checks; (e) The specific identification (i.e., the date and time of commencement and completion) of each time period of excess emissions and parameter monitoring exceedances tat occurs during periods other than startups, shutdowns, and malfunctions of the source; (f) The nature and cause of any malfunction (if know); the corrective action taken or preventive measures adopted; (g) The nature of the repairs or adjustment to the CMS that was inoperative or out of control; (h) The total process operating time during the reporting period; and (I) All procedures that are part of a quality control program developed and implemented for CMS?			

CHAPTER 8
COMMONLY ASKED QUESTIONS AND ANSWERS

Q: Am I a major source?

A: The term "major source" refers to a category of stationary sources that are regulated for emissions of hazardous air pollutants (HAP's) under Section 112 of the Clean Air Act. Your facility is a major source if it emits or has the potential to emit, after air pollution controls, 10 tons per year of any one hazardous pollutant or 25 tons per year of any combination of HAP's. Facilities that emit lesser quantities of HAP's are "area sources." The term "area" is used rather than "non-major" or "minor" to emphasize that while individual facilities are smaller, their aggregate emissions are still a concern, especially in urban areas containing many facilities. Ethylene oxide is designated as a hazardous air pollutant.

Q: In terms of the requirements of this standard, 40 CFR Part 63, Subpart O, does it matter whether I am a major or area source?

A: No. Some of the National Emission Standards for Hazardous Air Pollutants (NESHAP) do differentiate between major and area sources and some only regulate the major sources. However, this standard, 40 CFR Part 63, Subpart O (Sterilizer NESHAP), regulates both major and area sources.

Q: Does my ethylene oxide usage have an impact on the requirements of the Sterilizer NESHAP?

A: Yes. If your facility uses less than 1 ton of ethylene oxide per year (all consecutive 12-month periods after December 6, 1996), you are subject to only the recordkeeping requirements of the standard (Section 63.367). If you use 1 or more tons of ethylene oxide per year, you are also subject to the emission standards of the Sterilizer NESHAP. Which emission standards apply to you depend on whether or not you use 10 or more tons of ethylene oxide per year. Please note that how the standards apply to you is based on ethylene oxide usage, not ethylene oxide emissions. The basis here is different from that used to determine whether you are a major or area source.

Q: When do I need to comply with the Sterilizer NESHAP?

A: If the startup of your sterilization facility occurred on or before December 8, 1997, your compliance date is December 8, 1997. If your startup will be after December 8, 1997, your compliance date is the date of startup. As of your compliance date, you are required to meet all standards that apply to you, depending on your ethylene oxide usage (see Question 3).

If the Sterilizer NESHAP emission standards apply to your facility, you will need to conduct initial performance testing within 180 days of your compliance date or by June 8, 1998, if your compliance date is December 8, 1997. The performance testing is conducted with the methods and procedures in Sections 63.7 and 63.365. Performance testing will determine the values to be used for compliance monitoring at your facility. Monitoring requirements are described in Section 63.364 of the Sterilizer NESHAP and come into effect on the date of completion of the initial performance test.

Q: What does the Title V permit deferral I've heard about have to do with what I'm required to do for this standard (Sterilizer NESHAP)?

A: On June 3, 1996, the USEPA published an amendment to the Sterilizer NESHAP in the *Federal Register* (61 FR 27785). In its original form, the Sterilizer NESHAP required that subject sources using 1 ton or more obtain a Title V permit. The amendment revises Section 63.360(f) to state that subject sources which use 1 ton, but are not major or located at major sources, may be deferred by the applicable Title V permitting authority from the Title V permitting requirements for 5 years until December 9, 1999. Most States have indicated that they will grant these deferrals. This means that if you are an area source using 1 ton per year, you have until December 9, 2000, to submit your Title V permit application, unless your State agency specifies an earlier deadline.

The deferral of the Title V application deadline does NOT affect the compliance deadline of the Sterilizer NESHAP. Therefore, if your company is an area source using 1 ton, you must be in compliance with the emission standards by December 8, 1997.

Q: How does combining my emissions from two or more emissions points to one control device affect my initial compliance test and ongoing monitoring?

A: In certain circumstances, it is possible to combine the emissions flows from multiple emissions points to a single emissions control device (e.g., combine the emissions from the sterilizer vent and aeration room to a catalytic oxidizer). If such an approach were attempted, the owner or operator would need to obtain prior approval from the delegated State agency. In addition, during the initial compliance test, the emissions points would need to be isolated so that the monitoring parameters may be accurately determined. After initial compliance is determined, the emissions may be manifolded to a common control device provided that the monitoring parameter limits determined during the initial compliance test are not exceeded.

Q: I determined initial compliance with the aeration room vent standards by calculating the percent reduction in emissions, must I continue to calculate the percent reduction to satisfy the ongoing monitoring requirements?

A: The aeration room vent standards for sources using 10 or more tons of EO per year require either a 99 percent emission reduction or a maximum EO concentration of 1 ppmv. The standards do not require a source to commit to either approach. Therefore, it would be possible for a source to determine initial compliance with the standards by calculating their percent reduction in aeration room vent emissions, and then comply with the 1 ppmv concentration limit to show ongoing compliance.

CHAPTER 9
AVAILABLE IMPLEMENTATION MATERIALS

The following are several resources available to EO NESHAP implementation officials as well as to the regulated community. These resources have been prepared by a variety of sources. The listing of these sources in this chapter should not imply any endorsement by the U. S. Environmental Protection Agency. Unless noted in the referenced documents, the U. S. Environmental Protection Agency has not reviewed these documents, and is not responsible for their content.

Ethylene Oxide Sterilization (EtO) Facilities. in: NSR BACT Guidelines (an Internet-based publication). Texas Natural Resources Conservation Commission, Office of Policy and Regulatory Development. This Internet site may be found at

http://www.tnrcc.state.tx.us/air/nsr_permits/bact.htm

Ethylene Oxide Sterilizers. in: (an Internet-based publication). U. S. Environmental Protection Agency, Region 5. This Internet site may be found at

http://www.epa.gov/docs/ARD-R5/enforce/ethyl.htm

Model Implementation Plan for MACT Standards (draft No. 1). Illinois EPA. October 4, 1996.

National Emission Standards for Hazardous Air Pollutants for: Chromium Emissions from hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks; Ethylene Oxide Commercial Sterilization and Fumigation Operations; Perchloroethylene Dry Cleaning Facilities; and Secondary Lead Smelting: Final Amendment. in *Federal Register*: 61 FR 27785. June 3, 1996.

National Emission Standards for Hazardous Air Pollutants for: Chromium Emissions from hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks; Ethylene Oxide Commercial Sterilization and Fumigation Operations; Perchloroethylene Dry Cleaning Facilities; and Secondary Lead Smelting: Proposed Rule Amendment. in *Federal Register*: 60 FR 64002. December 13, 1995.

National Emissions Standards for Commercial Sterilization and Fumigation Facilities: Guidance Information. U. S. Environmental Protection Agency, Emission Standards Division. February, 1995. (Available on EPA's Technology Transfer Network)

New Regulation Controlling Air Emissions from Ethylene Oxide Commercial Sterilization and Fumigation. U. S. Environmental Protection Agency; Emission Standards Division. February, 1995. Publication Number: EPA-453/F-95-002. (Available on EPA's Technology Transfer Network)

AVAILABLE IMPLEMENTATION MATERIALS

National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations: Final Rule (40 CFR Parts 9 and 63, Subpart O). in *Federal Register*: 59 FR 62585. December 6, 1994.

Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations: Background Information for Final Standards. U. S. Environmental Protection Agency, Emission Standards Division. November, 1994. Publication Number: EPA-453/R-94-084b.

National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations: Proposed Rule (40 CFR Parts 9 and 63, Subpart O). in *Federal Register*: 59 FR 10591. March 7, 1994.

Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations: Background Information for Proposed Standards. U. S. Environmental Protection Agency, Emission Standards Division. October, 1992. Publication Number: EPA-453/D-93-016.

APPENDIX A

GLOSSARY OF TERMS

Administrator means the Administrator of the United States Environmental Protection Agency of his or her authorized representative (e.g., a State that has been delegated the authority to implement the provisions of 40 CFR part 63).

Aeration room means any vessel or room that is used to facilitate off-gassing of ethylene oxide at a sterilization facility.

Aeration room vent means the point(s) through which the evacuation of ethylene oxide-laden air from an aeration room occurs.

Area source means any stationary source of hazardous air pollutants that is not a major source as defined below in this appendix. Another term for area source is "nonmajor source."

Baseline temperature means any temperature at the outlet point of a catalytic oxidation unit control device or at the exhaust point from the combustion chamber for a thermal oxidation unit control device established during the performance test when the respective unit achieves at least 99-percent control of ethylene oxide emissions.

Chamber exhaust vent means the point(s) through which ethylene oxide-laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes.

Compliance date means the date by which a source subject to the emissions standards in § 63.362 is required to be in compliance with the standard.

Effective date means the date of promulgation in the *Federal Register* notice (December 6, 1994).

Initial startup date means the date when a source subject to the emissions standards in § 63.362 first begins operation of a sterilization process.

Major source means any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls in the aggregate, 10 tons per year or more of any hazardous air pollutant, or 25 tons per year or more of any combination of hazardous air pollutants.

Manifolding emissions means combining ethylene oxide emissions from two or more different vent types for the purpose of controlling these emissions with a single control device.

Maximum ethylene glycol concentration means any concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

Maximum liquor tank level means any level of scrubber liquor in the acid-water scrubber liquor recirculation tank established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

Operating parameter value means a minimum or maximum value established for a control device or process parameter which, if achieved by itself or in combination with one or more other operating parameter values, determines that an owner or operator is in continual compliance with the applicable emission limitation standard.

Oxidation temperature means the temperature at the outlet point of a catalytic oxidation unit control device or at the exhaust point from the combustion chamber for a thermal oxidation unit control device.

Parametric monitoring means monitoring of a specific operating parameter of the control device that demonstrates that the control device is operating under conditions that meet the standard.

Research or laboratory operation means an operation whose primary purpose is for research and development of new processes and products, that is conducted under the close supervision of technically trained personnel, and that is not involved in the manufacture of products for commercial sale in commerce, except in a de minimis manner.

Source(s) using less than 1 ton means source(s) using less than 907 kg (1 ton) of ethylene oxide within all consecutive 12-month periods after December 6, 1996.

Source(s) using 1 ton means source(s) using 907 kg (1 ton) or more of ethylene oxide within any consecutive 12-month period after December 6, 1996.

Source(s) using 1 to 10 tons means source(s) using 907 kg (1 ton) or more of ethylene oxide in any consecutive 12-month period but less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

Source(s) using less than 10 tons means source(s) using less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

Source(s) using 10 tons means source(s) using 9,070 kg (10 tons) or more of ethylene oxide in any consecutive 12-month period after December 6, 1996.

Sterilization chamber means any enclosed vessel or room that is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture, for the purpose of sterilizing and/or fumigating at a sterilization facility.

Sterilization chamber vent means the point (prior to the vacuum pump) through which the evacuation of ethylene oxide from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.

Sterilization facility means any stationary source where ethylene oxide is used in the sterilization or fumigation of materials.

Sterilization operation means any time when ethylene oxide is removed from the sterilization chamber through the sterilization chamber vent or the chamber exhaust vent or when ethylene oxide is removed from the aeration room through the aeration room vent.

APPENDIX B.
DETAILED TABLE OF CONTENTS OF THE REGULATION

Table B-1. Detailed Table of Contents of the Regulation

Section in regulation	Contents or Requirement
§ 63.360 Applicability	
§ 63.360(a)	Sources using ≥1 ton EO per year subject to rule (including subpart A)
§ 63.360(b)	Sources using <1 ton EO per year only subject to recordkeeping in § 63.367(c)
§ 63.360(c)	Exemption for beehive fumigation sources
§ 63.360(d)	Exemption for research and development sources
§ 63.360(e)	Exemption for medical facilities
§ 63.360(f)	Sources using ≥1 ton EO per year must obtain title V permit
§ 63.360(g)	Compliance dates (CD):
§ 63.360(g)(1)	• Startup before 12/8/97 ⇒ CD = 12/6/97
§ 63.360(g)(2)	• Startup after 12/8/97 ⇒ CD = startup date
§ 63.360(g)(3)	• Increase EO usage after 12/8/97 ⇒ CD = date of increase
§ 63.361 Definitions	
§ 63.361	Definitions of terms used in regulation
§ 63.362 Standards	
§ 63.362(a)	Comply with standards as of CD for source
§ 63.362(b)	Standards apply only during sterilization operation, not during malfunctions
§ 63.362(c)	Sterilization chamber vent (SCV) (sources using ≥ 1 ton) ⇒ 99 percent reduction
§ 63.362(d)	Aeration room vent (ARV) (sources using ≥ 10 tons) ⇒ 99 percent reduction or 1 ppmv EO
§ 63.362(e)	Chamber exhaust vent (CEV) standards:
§ 63.362(e)(1)	• Sources using ≥ 10 tons ⇒ manifold to SCV or ARV or 99 percent reduction
§ 63.362(e)(2)	• Sources using 1 to 10 tons ⇒ 5,300 ppmv EO; may manifold to SCV or 99 percent reduction (without manifolding)
§ 63.363 Compliance	
§ 63.363(a)	Initial performance test required within 180 days after CD
§ 63.363(b)	Determining compliance with SCV standard:

Table B-1. (continued)

Section in regulation	Contents or Requirement
§ 63.363(b)(1)	• Use test method in § 63.365(b)(1) to determine efficiency
§ 63.363(b)(1)(I)	•• Establish site-specific operating parameters for acid-water scrubbers ⇒ ethylene glycol concentration [EG] or scrubber liquor tank level
§ 63.363(b)(1)(ii)	•• Establish site-specific operating parameter for catalytic/thermal oxidizers ⇒ baseline temperature
§ 63.363(b)(2)	• Parameter violations
§ 63.363(c)	Determining compliance with ARV standard:
§ 63.363(c)(1)	• Use test method in § 63.365(c)(1) to determine EO concentration; use § 63.365(d)(1) to determine efficiency
§ 63.363(c)(2)	• Establish site-specific operating parameter for catalytic/thermal oxidizers ⇒ baseline temperature [T]
§ 63.363(c)(3)	• Parameter violations
§ 63.363(d)	Determining compliance with CEV standard for sources using ≥10 tons:
§ 63.363(d)(1)	• If manifolding to SCV or ARV, comply with those parameters
§ 63.363(d)(2)	• If using dedicated control device:
§ 63.363(d)(2)(I)	•• Use test method in § 63.365(d)(2) to determine efficiency; establish site-specific operating parameters for acid-water scrubbers ⇒ [EG] or scrubber liquor tank level; establish operating parameter for catalytic/thermal oxidizers ⇒ [T]
§ 63.363(d)(2)(ii)	•• Parameter violations
§ 63.363(e)	Determining compliance with CEV standard for sources using 1 to 10 tons:
§ 63.363(e)(1)	• If manifolding to SCV, comply with those parameters
§ 63.363(e)(2)	• If using dedicated control device:
§ 63.363(e)(2)(I)	•• Use test method in § 63.365(c)(2) to determine EO concentration [EO]
§ 63.363(e)(2)(ii)	•• Use test method in § 63.365(d)(2) to determine efficiency; establish site-specific operating parameters for acid-water scrubbers ⇒ [EG] or scrubber liquor tank level; establish operating parameter for catalytic/thermal oxidizers ⇒ [T]
§ 63.363(e)(3)	• Parameter violations
§ 63.363(f)	Compliance procedures for sources using other control devices

Table B-1. (continued)

Section in regulation	Contents or Requirement
§ 63.364 Monitoring	
§ 63.364(a)	Sources must comply with this section and subpart A
§ 63.364(b)	Acid-water scrubber monitoring:
§ 63.364(b)(1)	• [EG] - weekly
§ 63.364(b)(2)	• Scrubber liquor tank level - weekly
§ 63.364(c)	Catalytic/thermal oxidizer monitoring:
§ 63.364(c)(1)	• SCV ⇒ [T] over cycle length; average every third cycle
§ 63.364(c)(2)	• ARV ⇒ [T] over 1 hour; average every third hour
§ 63.364(c)(3)	• CEV ⇒ [T] over cycle length
§ 63.364(c)(4)	• Verify accuracy of [T] monitor every 6 months
§ 63.364(d)	Other control device monitoring according to § 63.365(g)
§ 63.364(e)	Monitoring of [EO]:
§ 63.364(e)(1)	• ARV - [EO] hourly; average every third hour; install gas chromatograph and calibrate daily
§ 63.364(e)(2)	• CEV (1 to 10 tons) - [EO] before chamber exhaust activation; install gas chromatograph and calibrate daily
§ 63.364(f)	If manifolding, comply with parameters for that device
§ 63.365 Test Methods and Procedures	
§ 63.365(a)	Sources subject to this section and subpart A
§ 63.365(b)	SCV - efficiency and parameter determination:
§ 63.365(b)(1)	• First evacuation of SCV - efficiency and parameter
§ 63.365(b)(2)	• Last evacuation of SCV - efficiency and parameter
§ 63.365(c)	Concentration determination for ARV and CEV (1 to 10 tons):
§ 63.365(c)(1)	• ARV - [EO]
§ 63.365(c)(2)	• CEV (1 to 10 tons) - [EO]
§ 63.365(d)	Efficiency and parameter determination for ARV and CEV:
§ 63.365(d)(1)	• ARV - efficiency
§ 63.365(d)(2)	• CEV (not manifolded)

Table B-1. (continued)

Section in regulation	Contents or Requirement
§ 63.365(e)	Parameter determination for acid-water scrubber:
§ 63.365(e)(1)	• [EG] (any vent type)
§ 63.365(e)(2)	• Scrubber liquor tank level (any vent type)
§ 63.365(f)	Temperature determination for catalytic/thermal oxidizer:
§ 63.365(f)(1)	• SCV
§ 63.365(f)(2)	• ARV
§ 63.365(f)(3)	• CEV
§ 63.365(g)	Efficiency and parameter determination for other control devices
§ 63.365(h)	Alternative to gas chromatography for ARV or CEV standards
§ 63.366 Reporting	
§ 63.366(a)	Sources subject to this section and subpart A; content and submittal dates for summary, excess emissions, and monitoring system performance reports
§ 63.366(b)	Construction/reconstruction reporting
§ 63.366(c)	Notification reports
§ 63.367 Recordkeeping	
§ 63.367(a)	Sources subject to this section and subpart A
§ 63.367(b)	Sources using 1 to 10 tons maintain records of EO usage on 12-month rolling basis
§ 63.367(c)	Sources using < 1 ton maintain records of EO usage on 12-month rolling basis

APPENDIX C.
LIST OF KNOWN FACILITIES

Table C-1. List of Known Facilities

Facility name	Parent company	City	State
Travenol Laboratories, Inc.	American Hospital Supply	Mountain Home	AK
Alabama Dept. Of Agriculture		Montgomery	AL
Arkansas History Commission		Little Rock	AR
W.L. Gore & Assoc., Inc.		Flagstaff	AZ
Procter & Gamble		Phoenix	AZ
The Heard Museum		Phoenix	AZ
Botanicals International	Zuellig Botanicals, Inc.	Long Beach	CA
Cal-Compack Foods		Santa Ana	CA
Farmer Bros. Co.		Torrance	CA
Santa Maria Chili, Inc.		Santa Maria	CA
Allergan Pharmaceuticals		Irvine	CA
Maurry Biological Co., Inc.		Los Angeles	CA
Barnes Hind, Inc.		Sunnyvale	CA
Medlon, Inc.		Burbank	CA
Ways & Means, Inc.		San Rafael	CA
IVAC Corporation		San Diego	CA
American Bentley	American Hospital Supply	Irvine	CA
American Edwards Laboratories	American Hospital Supply	Irvine	CA
American Pharmaseal	American Hospital Supply	Irwindale	CA
Shiley, Inc.	Pfizer	Irvine	CA
3M		Goleta	CA
Abco Laboratories		Concord	CA
Micro-Biotrol, Inc.		Vernon	CA
Sterilization Services of Calif.		Anaheim	CA
Lowie Museum of Anthropology	University of California	Berkeley	CA
Telectronics		Englewood	CA
Cobe Laboratories		Lakewood	CO
Valleylab, Inc.	Pfizer	Boulder	CO

Table C-1. (continued)

Facility name	Parent company	City	State
Acme United Corp.		Stratford	CT
Becton, Dickinson & Company		Canaan	CT
Critikon, Inc.	Johnson & Johnson	Southington	CT
United States Surgical Corporation		North Haven	CT
Cryomedics, Inc.		Trumbull	CT
Davis & Geck, Inc.	American Cyanamid Company	Danbury	CT
Delaware Dept. Of Agriculture		Dover	DE
EI DuPont		Wilmington	DE
Cordis Corp.		Miami	FL
Critikon, Inc.	Johnson & Johnson	Tampa	FL
Sterile Design, Inc.		Tampa	FL
Seamless Hospital Products Co.		Ocala	FL
Steridyne Corp,.		Riviera Beach	FL
Kendall Company		Augusta	GA
C.R. Bard, Inc.		Covington	GA
Micro-Biotrol, Inc.		Smyrna	GA
Sterilization Services of Georgia		Atlanta	GA
Univ. Of Hawaii Hamilton Library		Honolulu	HI
Clinton Corn Processing Co.	ADM	Clinton	IA
Tone Brothers, Inc.		Des Moines	IA
Parks Library		Ames	IA
Abbott Laboratories		North Chicago	IL
Abbott Laboratories		North Chicago	IL
Travenol Laboratories, Inc.	American Hospital Supply	Round Lake	IL
Elgin Medical Corporation		Elgin	IL
Araclean Services, Inc.		LaGrange	IL
Micro-Biotrol, Inc.		Willowbrook	IL
Medsteril, Inc.		Mundelein	IL
Graham Center Archives	Wheaton College	Wheaton	IL

Table C-1. (continued)

Facility name	Parent company	City	State
Eli Lilly and Co.		Indianapolis	IN
Eli Lilly and Co.		Indianapolis	IN
Cook Inc.		Bloomington	IN
Reynier's Germfree Building		Notre Dame	IN
Kendall Company		Franklin	KY
Charles River Laboratories, Inc.		Wilmington	MA
Portex, Inc.		Wilmington	MA
C.R. Bard, Inc.		Billerica	MA
EI DuPont		Billerica	MA
Findley Research, Inc.		Fall River	MA
American Antiquarian Society		Worcester	MA
New Bedford Whaling Museum		New Bedford	MA
Conservation Lab	Old Sturbridge Village	Sturbridge	MA
First Church of Christ Scientist		Boston	MA
Maryland Dept. Of Agriculture		Annapolis	MD
Baltimore Spice	Durkee Foods	Garrison	MD
McCormick & Co., Inc.		Hunt Valley	MD
BBL Microbiology Systems	Becton Dickinson	Cockeysville	MD
Frederick Cancer Research Facility	NCI	Frederick	MD
The Jackson Laboratory		Bar Harbor	ME
Charles River Laboratories, Inc.		Portage	MI
General Spice, Inc.		Detroit	MI
Parke-Davis	Warner-Lambert Co.	Rochester	MI
The UpJohn Company		Kalamazoo	MI
Sarns, Inc.	3M Co.	Ann Arbor	MI
Tri-State Hospital Supply Corp.		Howell	MI
The UpJohn Company		Kalamazoo	MI
The UpJohn Company		Kalamazoo	MI
Medtronic, Inc. Rice Creek Facility	Medtronic, Inc.	Minneapolis	MN

Table C-1. (continued)

Facility name	Parent company	City	State
Daig Corporation		Minnetonka	MN
SciMed Life Systems, Inc.		Plymouth	MN
PRL	Medtronic, Inc.	Coon Rapids	MN
American Medical Systems, Inc.	Pfizer	Minnetonka	MN
A.D.T. Lab Industries, Inc.		Lakeville	MN
Spicecraft, Inc.		Gerald	MO
Hollister, Inc.		Kirksville	MO
Diagnostic Division	Mallinckrodt, Inc.	Maryland Hts	MO
Monsanto Company		St. Louis	MO
Midwest Sterilization Corp.		Cape Girardeau	MO
Flavorite Laboratories, Inc.		Horn Lake	MS
Travenol Laboratories, Inc.	American Hospital Supply	Cleveland	MS
NC Dept. Of Agriculture		Raleigh	NC
Charles River Laboratories, Inc.		Raleigh	NC
Abbott Laboratories		Laurinburg	NC
Abbott Laboratories		Rocky Mount	NC
Arrow International		Randleman	NC
Edward Weck and Company, Inc.		RTP	NC
IVAC Corporation		Creedmoor	NC
Baltimore Spice	Durkee Foods	Grand Forks	ND
Concord Laboratories, Inc.		Keene	NH
Millipore Corporation		Jaffrey	NH
Rutgers-Kilmer Facility	NJ Department of Agriculture	New Brunswick	NJ
Meer Corporation		North Bergen	NJ
American Hoechst Corporation		Somerville	NJ
E.R. Squibb & Sons	Squibb	North Brunswick	NJ
Leeming/Pacquin	Pfizer, Inc.	Parsippany	NJ
Squibb Corporation		Lawrenceville	NJ
C.R. Bard, Inc.		Murray Hill	NJ

Table C-1. (continued)

Facility name	Parent company	City	State
Vernitron Medical Products		Carlstadt	NJ
Ethicon, Inc.	Johnson & Johnson	Somerville	NJ
Johnson & Johnson Products, Inc.	Johnson & Johnson	New Brunswick	NJ
Johnson & Johnson Products, Inc.	Johnson & Johnson	New Brunswick	NJ
Johnson & Johnson Products, Inc.	Johnson & Johnson	New Brunswick	NJ
Overseas Spice Co.		Newark	NJ
Micro-Biotrol, Inc.		Boundbrook	NJ
ETO Sterilization, Inc.		Linden	NJ
N. Am. Sterilization & Package Co		Sparta	NJ
Pacon Manufacturing Corporation		South Planfield	NJ
Archives & History Center	United Methodist Church	Madison	NJ
Ethicon, Inc.	Johnson & Johnson	Albuquerque	NM
Baltimore Spice	Durkee Foods	Sparks	NV
Charles River Laboratories, Inc.		Kingston	NY
direrle Laboratories	American Cyanamid Company	Pearl River	NY
Bristol-Myers Company		East Syracuse	NY
G.C. Hanford Manufacturing Co.		Syracuse	NY
H.W. Andersen Products		Oyster Bay	NY
MCC Division	Mallinckrodt, Inc.	North Argyle	NY
Castle	Sybron Corp.	Rochester	NY
Deknatel Division	Pfizer Hospital Products Group	Queens Village	NY
Ethox Corp.		Buffalo	NY
Chesebrough-Pond’s	Sherwood Medical Company	Sherburne	NY
Morris J. Golombeck, Inc.		Brooklyn	NY
Sterilization Tech. Services, Inc.		Rush	NY
Medical Sterilization, Inc.		Syosset	NY
Ben Venue Laboratories, Inc.		Bedford	OH
Medex, Inc.		Hilliard	OH
Dravon Medical, Inc.		Clackamas	OR

Table C-1. (continued)

Facility name	Parent company	City	State
Durkee Famous Foods	Durkee Foods	Bethlehem	PA
Merck Sharp & Dohme		West Point	PA
Sterling Drug, Inc.		Myerstown	PA
Wyeth Laboratories, Inc.		West Chester	PA
Wyeth Laboratories, Inc.		Marietta	PA
The West Co. Jersey Shore Facility		Jersey Shore	PA
Burron Medical, Inc.		Allentown	PA
Sharpoint, Inc.		Sinking Spring	PA
Araclean Services, Inc.		Scranton	PA
Squibb Manufacturing, Inc.		Humacao	PR
Lederle Parenteral, Inc.	American Cyanamid Company	Carolina	PR
Abbott Laboratories		Barceloneta	PR
Travenol Laboratories, Inc.	American Hospital Supply	Aguada	PR
Travenol Laboratories, Inc.	American Hospital Supply	Aibonito	PR
Travenol Laboratories, Inc.	American Hospital Supply	Jayuya	PR
Davis & Geck, Inc.	American Cyanamid Company	Manati	PR
Millipore Cidra, Inc.		Cidra	PR
MED REL, Inc.	Medtronic, Inc.	Humacao	PR
C.R. Bard, Inc.		Las Piedras	PR
American V. Mueller	American Hospital Supply	Anasco	PR
American Edwards Laboratories	American Hospital Supply	Anasco	PR
U.S. Surgical Corporation		Ponce	PR
Medtronic Puerto Rico, Inc.	Medtronic, Inc.	Villalba	PR
C.R. Bard, Inc.		Cranston	RI
Ethide Laboratories, Inc.		Coventry	RI
Travenol Laboratories, Inc.	American Hospital Supply	Kingstree	SC
Smith and Nephew		Columbia	SC
3M		Brookings	SD
Tennessee Dept. Of Agriculture		Nashville	TN

Table C-1. (continued)

Facility name	Parent company	City	State
American Pharmaseal	American Hospital Supply	Johnson City	TN
Sterilization Services of Tennessee		Memphis	TN
Paso Pak Chili Company, Inc.		Fabens	TX
Baltimore Spice	Durkee Foods	Anthony	TX
Alcon Laboratories, Inc.		Forth Worth	TX
Sherwood Medical Company		Commerce	TX
Alva Medical	Mallinckrodt, Inc.	Angleton	TX
Argon Medical Corporation	Squibb	Athens	TX
U.S. Clinical Products, Inc.		Richardson	TX
Ethicon, Inc.	Johnson & Johnson	San Angelo	TX
Seamless Hospital Products Co.		El Paso	TX
Fort Belknap Archives, Inc.		Graham	TX
Permian Basin Petroleum Museum		Midland	TX
Abbott Laboratories		Salt Lake City	UT
Dept. of Ag & Consumer Services	Comonwealth of Virginia	Richmond	VA
Old Mansion, Inc.		Richmond	VA
Sterile Concepts, Inc.		Richmond	VA
Lukens Corporation		Lynchburg	VA
Gambro, Inc.		Newport News	VA
Crescent Foods		Seattle	WA
Action Medical Systems, Inc.		Kirkland	WA
Foran Spice Company		Oak Creek	WI
West Virginia Dept. Of Agriculture		Charleston	WV

TECHNICAL REPORT DATA

(Please read Instructions on reverse before completing)

1. REPORT NO.	2.	3. RECIPIENT'S ACCESSION NO.
EPA 456/R-97-004		

4. TITLE AND SUBTITLE	5. REPORT DATE
Ethylene Oxide Commercial Sterilization and Fumigation Operations NESHAP Implementation Document	September 1997
	6. PERFORMING ORGANIZATION CODE

7. AUTHOR(S)	8. PERFORMING ORGANIZATION REPORT NO.
David G. Hearne Susan J. Shrager	4203-31-02

9. PERFORMING ORGANIZATION NAME AND ADDRESS	10. PROGRAM ELEMENT NO.
Midwest Research Institute 5520 Dillard Road, Suite 100 Cary, NC 27511	11. CONTRACT/GRANT NO. 68-D3-0031, WA 31

12. SPONSORING AGENCY NAME AND ADDRESS	13. TYPE OF REPORT AND PERIOD COVERED
Office of Air Quality Planning and Standards Office of Air and Radiation U.S. Environmental Protection Agency Research Triangle Park, NC 27711	Final
	14. SPONSORING AGENCY CODE EPA/200/04

15. SUPPLEMENTARY NOTES

Project Officer is Gilbert Wood, Mail Drop 12, (919) 541-5272

16. ABSTRACT

National emissions standards to control emissions of HAP from new and existing ethylene oxide commercial sterilization and fumigation operations were promulgated in 1994. This document contains information to assist State and local air pollution control agencies as well as the regulated community in the implementation of these standards. This document provides a common sense summary of the NESHAP requirements, describes the most frequently encountered emissions points, and describes the most commonly used emissions control devices. Sample inspection sheets are also provided as is a bibliography of Federal, State and private sources of additional information related to these standards.

17. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
Air pollution Air pollution control National emissions standards Hazardous air pollutants Ethylene oxide Commercial sterilization and fumigation industry Implementation guidance	Air pollution control Ethylene oxide Stationary sources	13B

18. DISTRIBUTION STATEMENT	19. SECURITY CLASS *(Report)*	21. NO. OF PAGES
Unlimited	Unclassified	70
	20. SECURITY CLASS *(Page)*	22. PRICE
	Unclassified	